

## Nuclear Regulatory Commission

## § 32.57

(ii) Levels of radiation in excess of 5 microgray (0.5 millirad) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, if the device contains promethium-147; and

(iii) Any other criteria specified in the license issued under § 32.53.

(d) No person licensed under § 32.53 shall transfer to persons generally licensed under § 31.7 of this chapter, or under an equivalent general license of an Agreement State:

(1) Any luminous safety device tested and found defective under any condition of a license issued under § 32.53, or paragraph (b) of this section, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) Any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (b)(2) of this section, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.53; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (b)(2) and (d)(2)(i) of this section and any other criteria that may be required as a condition of the license issued under § 32.53.

[77 FR 43693, July 25, 2012]

### **§ 32.56 Same: Material transfer reports.**

(a) Each person licensed under § 32.53 shall file an annual report with the Director, Office of Federal and State Materials and Environmental Management Programs, ATTN: Document Control Desk/GLTS, by an appropriate method listed in § 30.6(a) of this chapter, which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under § 31.7 of this chapter. The report must identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report must cover the year ending June 30 and must be filed

within thirty (30) days thereafter. If no transfers have been made to persons generally licensed under § 31.7 of this chapter during the reporting period, the report must so indicate.

(b) Each person licensed under § 32.53 shall report annually all transfers of devices to persons for use under a general license in an Agreement State's regulations that are equivalent to § 31.7 of this chapter to the responsible Agreement State agency. The report must state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. If no transfers have been made to a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State agency upon request of the agency.

[77 FR 43694, July 25, 2012]

### **§ 32.57 Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer.**

An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if:

(a) The applicant satisfies the general requirements of § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of americium 241 or radium-226 in the source;

(2) Details of construction and design;

(3) Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

(4) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005

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microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

(5) Details of quality control procedures to be followed in manufacture of the source;

(6) Description of labeling to be affixed to the source or the storage container for the source;

(7) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.

(c) Each source will contain no more than 5 microcuries of americium-241 or radium-226.

(d) The Commission determines, with respect to any type of source containing more than 0.005 microcurie of americium-241 or radium-226, that:

(1) The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 or radium-226 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(2) The source has been subjected to and has satisfactorily passed appropriate tests required by paragraph (e) of this section.

(e) The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to tests as follows:

(1) The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.

(2) The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion.

(3) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining

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compliance with the criteria in paragraph (e)(4) of this section.

(4) Source designs are rejected for which the following has been detected for any unit: Removal of more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

[30 FR 8192, June 26, 1965, as amended at 43 FR 6923, Feb. 17, 1978; 72 FR 55928, Oct. 1, 2007; 73 FR 42674, July 23, 2008; 77 FR 43694, July 25, 2012]

### § 32.58 Same: Labeling of devices.

Each person licensed under § 32.57 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:<sup>1</sup>

The receipt, possession, use, and transfer of this source, Model, Serial No., are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION-RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE

(Name of manufacturer or initial transferor)

[72 FR 55929, Oct. 1, 2007]

### § 32.59 Same: Leak testing of each source.

Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under § 31.8 of this chapter or under

<sup>1</sup>Sources licensed under § 32.57 before January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.